

## **Remarks**

### **I. Status of the Application and Claims**

As originally filed in the United States, the present application had a total of 16 claims. In a Preliminary Amendment filed by Applicants on March 14, 2000, all claims were canceled and new claims 17-33 were added. As a result of a restriction requirement, claims 24-33 were withdrawn from consideration. Thus, the claims pending at the time the present Office Action was issued were claims 17-33. Applicants have canceled these claims herein and have introduced new claims 34-43.

### **II. The Amendments**

New claims 34-43 correspond closely to canceled claims 17-33. For the most part, claim language has been changed in accordance with suggestions by the Examiner. Claims 34 and 35 are supported by original claim 17, paragraph (b). This has been divided into two separate claims, the first directed to a polypeptide having the amino acid sequence of SEQ ID NO:2 and the second directed to a polynucleotide consisting of a nucleotide sequence encoding this polypeptide. Standard transitional patent terminology is used in the claims. In addition, claim 41 now refers to a "second" polynucleotide and claims 42 and 43 refer to oligonucleotides. These terms were introduced to help distinguish the claimed polynucleotides from other polynucleotides also recited in the claims.

Claim 36 is supported by paragraph (a) of original claim 17 and now requires a polynucleotide encoding a protein with 95% identity to SEQ ID NO:2. Support for 95% homology may be found on page 5 of the specification, lines 12-17.

Support for new claim 37 may be found in original claim 20. The phrase "degenerate variant" has been used in accordance with the suggestion of the Examiner appearing on page 3 of the Office Action, item 5.

Support for new claim 38 may be found on page 4 of the specification, lines 8-10, and support for claim 39 may be found on page 11, lines 6-9.

Support for new claim 40 may be found in Example 4 of the application, beginning on page 19, line 9 and concluding on page 20, line 3.

Support for new claim 41 may be found in cancelled claim 17, paragraph (c).

Support for claim 42 may be found in cancelled claim 17, paragraph (d), and on page 4 of the specification, line 27- page 5, line 6.

Support for new claim 43 may be found in original claim 22, paragraph (ii).

The amendments described above do not add new matter to the application and their entry is therefore respectfully requested.

### **III. Objection to Drawings**

On page 2 of the Office Action, the Examiner points out that there are certain defects in the Drawings that have been submitted. Applicants will file corrected formal drawings upon the allowance of claims.

### **IV. Informalities of the Specification**

On page 2 of the Office Action, the Examiner objects to the excessive space left on pages 2 and 22 of the specification. In addition, the Examiner objects to the inclusion of German text in Figure 1. In response, Applicants have deleted the extra space on pages 2 and 22. The German text in Figure 1 will be deleted at the time corrected formal drawings are submitted.

## **The Rejections**

### **I. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

On pages 3 and 4 of the Office Action, several rejections are made based upon 35 U.S.C. § 112, second paragraph. In items 4-7, the Examiner alleges that the following phrases are indefinite: "at least one sequence" (item 4); "corresponds to the sequence (i) within the degeneration range of the genetic code" (item 5); "hybridizes" (item 6); and "functionally

neutral sense mutations" (item 7). Since all of these phrases have been eliminated from the claims introduced herein, Applicants submit that these rejections have been obviated.

In items 8 and 9, the Examiner rejects claim 23 based upon the allegation that it contains confusing language with respect to the deposited vector. Applicants believe that the present claims referring to vectors, *i.e.*, claims 38 and 39, use language which is more clear and that they should meet the requirements of 35 USC §112, second paragraph.

## **II. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph**

On pages 4-9 of the Office Action, the Examiner rejects claims under 35 U.S.C. §112, first paragraph. The rejections are set forth in items 10-12. Below, Applicants respond to each allegation.

### **A. Rejections in Item 10**

It item 10, the Examiner rejects claims 17-19, 22 and 23 based upon the allegation that the specification does not contain sufficient disclosure to justify a claim to DNA sequences that have at least 15 successive bases encoding a polypeptide having an amino acid sequence 70% identical to the sequence of SEQ ID NO:2.

In response, Applicants submit that the claims introduced herewith are much more limited in scope. The broadest of the present claims not only requires 95% structural identity but also requires that the encoded polypeptide have essentially the same pyruvate oxidase activity as the protein of SEQ ID NO:2. Applicants submit that a claim of the present scope fully meets the requirements of 35 U.S.C. § 112, first paragraph.

### **B. Rejections in Item 11**

The rejection set forth in item 11 is similar to that in item 10. Specifically, the Examiner alleges that the specification does not enable the full scope of original claim 22.

In response, Applicants again point out that the present claims are of considerably more restricted scope. Also, the written description and enablement requirements of patentability should not be confused. The written description requirement is concerned with

whether one of skill in the art can identify whether a particular polynucleotide or polypeptide falls within the scope of a claim. The present claims require that polynucleotides encode a protein which has at least a 95% sequence identity with SEQ ID NO:2 and which has essentially identical pyruvate oxidase activity. Thus, there are clear criteria for determining whether a polynucleotide is encompassed within the claimed subject matter and there should not be a significant issue with regard to written description.

The issue with respect to enablement is whether sufficient information is provided so that one of skill in the art could make and use every species within the scope of a claim. In the present case, Applicants submit that the construction of any polynucleotide falling within the scope of the present claims would be well within the skill of most molecular biologists. Thus, there should not be a problem with respect to the enablement of the claims as amended herein.

#### **C. Rejection of Claims in Item 12**

It item 12, the Examiner rejects claims directed to pCR2.1poxBint alleging that the vector must be deposited to meet the enablement requirement of patentability and that a Declaration must be submitted concerning the terms of the deposit.

Applicants respectfully traverse this rejection.

Although, as set forth on page 14 of the specification, lines 23-28, Applicants deposited bacteria containing the claimed vector under the terms of the Budapest Treaty, it is submitted that one of skill in the art could construct the pCR2.1poxBint plasmid using the information provided in the specification and would not need to resort to the deposit. Examples 1 and 2 on pages 15-19 of the application provide a detailed description of a method for obtaining the poxB gene from a readily available bacterial strain, *Corynebacterium glutamicum*. Methods for amplifying the gene and for incorporating it into an integration vector are set forth in Example 3. This includes a description of primers that can be used for PCR amplification. The vector itself has been described in the literature (see page 18, lines 23-26) and a map showing the important elements present in the vector is shown as Figure 1. Apart from the poxB gene itself, all of the elements present in the vector

are readily available in the art, and the construction of the plasmid, given the information provided, should not present a major problem to an ordinary molecular biologist.

In light of these considerations, Applicants submit that the enablement requirement of patentability has been met even without the deposited plasmid. It is therefore respectfully requested that the present rejection be withdrawn.

### **III. Rejection of Claims Under 35 U.S.C. § 102, First Paragraph**

On page 9 of the Office Action, the Examiner rejects claims 17-19 under 35 U.S.C. § 102(b) as being anticipated by Redenbach, *et al.* (*Mol. Microbiol.* 21; 77-96). It is alleged that the reference teaches a polynucleotide that has 15 successive bases that are identical to bases 1735-1750 of SEQ ID NO:1, and that it was shown in the reference that these could be inserted into a replicable vector.

Applicants respectfully traverse this rejection for the claims as amended herein.

The reference by Redenbach does not disclose a nucleotide sequence encoding the *poxB* gene product as set forth in SEQ ID NO:2. Similarly, it does not disclose SEQ ID NO:1, a degenerate variant thereof, or any protein having pyruvate oxidase activity which is at least 95% structurally identical to the protein of SEQ ID NO:2. Therefore, this reference is not anticipatory of any of the claims presently pending in the application.

### **Conclusion**

In light of the amendments and discussion above, Applicants submit that all of the Examiner's rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims presently pending in the application be allowed.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (703) 905-2173.

Respectfully submitted,

PILLSBURY WINTHROP LLP

By: Michael A. Sanzo  
Michael A. Sanzo  
Reg. No. 36,912  
Attorneys for Applicants

Date: July 25, 2001

1600 Tysons Boulevard  
McLean, Virginia 22102  
(703) 905-2000